JUN 1 0 2004

K033552

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Jax-tcp

Contact Person and Address
Kim Kelly
Project Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc., Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-6566

Device Description
JAX-tcp is a single-use bone void filler consisting of two components: surgical grade β-tricalcium phosphate granules and a hydrogel, used as a handling medium. The product is supplied sterile in quantities ranging from 1cc to 30cc.

Device Classification Name & Product Code
Resorbable calcium salt bone void filler device (§888.3045): Orthopedics/87/MQV

Indications for Use
The Jax-tcp granules may be used alone or can be mixed with the gel to create a cohesive mass that can be applied to the defect site. The gel is contradicted for use without the use of the granules. When used together, the granules and gel should be combined in a 1:1 ratio.

JAX-tcp is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. JAX-tcp is indicated to be gently packed into bony voids or gaps of the skeletal system, (*i.e.*, the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. JAX-tcp provides a filler that is resorbed and is replaced with bone during the healing process.

Performance Data
A review of the test data indicated that JAX-tcp is equivalent to other predicate calcium salt based bone void fillers currently used clinically.

Substantial Equivalence Information
The intended use; base material of the granules; use of a hydrogel; and select performance properties of the Jax-tcp product are substantially equivalent to commercially available predicate bone void filler products. The product is adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Ms. Kim P. Kelly
Project Manager, Regulatory & Clinical Affairs
Smith & Nephew, Inc.
Orthopaedic
1450 Brooks Road
Memphis, TN 38116

Re: K033552
Trade Name: Jax-tcp
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: April 30, 2004
Received: May 3, 2004

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K033552

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033552

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ____X____ OR Over-The Counter Use _____
(Per 21 CFR 801.109)